Biotechnology Careers

Quality Assurance Auditors

What They Do

Quality Assurance Auditors make sure a manufacturing facility is performing efficiently and producing quality products. These workers complete tests during manufacturing to make certain that the process is in compliance with company and industry methods and standards. The biotechnology industry must be diligent complying with regulations that are designed to protect the public. The Food and Drug Administration (FDA) approves both the ingredients in a drug as well as the specific manufacturing process used to make the drug. Quality Assurance Auditors must be familiar with FDA and government regulations in order to observe and document that the manufacturing company is following approved production procedures.

Some Quality Assurance Auditors work in process validation verifying that each phase in the production process follows the specific procedures in the Good Manufacturing Practices (GMPs). If there are any deviations from approved procedures, they must record what took place. They must also sign-off on each phase of the production process to document that proper procedures were followed. Quality Assurance Auditors use the cGMPs (current Good Manufacturing Processes) documentation to correct inadequacies in production records to furnish the most accurate instructions.

Quality Assurance Auditors may also oversee the proper storage of raw materials. They may also inspect equipment to ensure that it is operating properly within established guidelines.

Quality Assurance Auditors must maintain excellent records, since they write detailed reports that document each step of the production process.

*Quality Assurance Auditors in the biotech industry share characteristics of Industrial Engineering Technicians. Detailed descriptions of these occupations may be found in the Occupational Information Network (O*NET) at online.onetcenter.org.*

Important skills, knowledge, and abilities include:

- Production and Processing – Knowledge of raw materials, production processes, quality control, costs, and other techniques for maximizing the effective manufacture and distribution of goods.
- Engineering and Technology – Knowledge of the practical application of engineering science and technology. This includes applying principles, techniques, procedures, and equipment to the design and production of various goods and services.
- Mathematics – Knowledge of arithmetic, algebra, geometry, calculus, statistics, and their applications.
- Reading Comprehension – Understanding written sentences and paragraphs in work related documents.
- Quality Control Analysis – Conducting tests and inspections of products, services, or processes to evaluate quality or performance.
- Information Ordering – The ability to arrange things or actions in a certain order or pattern according to a specific rule or set of rules (e.g., patterns of numbers, letters, words, pictures, mathematical operations).

EDD Employment Development Department State of California
LMID Labor Market Information Division "Your Information Source"

Quality Assurance Auditors

Training/Requirements

- Bachelor's degree in the biosciences or another scientific discipline.
- Up to two years of experience in biological or pharmaceutical manufacturing.

What's the California Job Outlook?

While the Bureau of Labor Statistics does not collect data on Quality Assurance Auditors, the occupation listed below is found in the biotechnology industry and has similar duties. The California outlook and wages figures are drawn from all industries and represent an occupation comparable to Quality Assurance Auditors.

Standard Occupational Classification	Estimated Number of Workers 2002	Estimated Number of Workers 2012	Average Annual Openings	2005 Wage Range (per hour)
Industrial Engineering Technicians				
17-3026	6,000	6,900	220	$18.48 to $29.77

These figures do not include self-employment.
***Average annual openings** include new jobs plus openings due to separations.*
Source: www.labormarketinfo.edd.ca.gov , Employment Projections by Occupation and OES Employment & Wages by Occupation, Labor Market Information Division, Employment Development Department.

Additional Sources of Information

Institute of Quality Assurance
www.iqa.org

Occupational Information Network (O*NET)
http://online.onetcenter.org

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